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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/678,379

10/06/2003

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01/22/2007

EXAMINER

LOPEZ, AMADEUS SEBASTIAN

ART UNIT

PAPER NUMBER

3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/678,379	<b>Applicant(s)</b> VANDERIPE, DONALD R.	
	<b>Examiner</b> Amadeus S. Lopez	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/04/2006</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 3-6 have been considered but are moot in view of the new ground(s) of rejection.

### ***Response to Amendment***

The examiner acknowledges the amendments made to the specification and hereby withdraws the objections as set forth in the previous office action.

### ***Information Disclosure Statement***

The examiner has considered all references disclosed within the Information Disclosure Statement filed on. 11/04/2006.

### ***Claim Objections***

Claim 3 is objected to because of the following informalities:

In line 6 of the claim, the word "complimentary" should be deleted and replaced with -- complementary --. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear from the claim language as to what structural elements are being used to determined that "a 50-90% or more washout of nitrogen from the body and body water and a subsequent washout of nitrogen from the affected

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tissues and mitochondria permits the return of ischemic tissues to a state of oxidative metabolism," has occurred.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what time frame would be sufficient and what the applicant intends when stating that the "treatment is implemented as soon as possible."

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-6 are rejected as obvious over Kumar et al (2003/013844) in view of Bird et al (3688794).

As to claim 3, Kumar et al disclose a process for treating reversible blood vessel occlusions in a human being who has suffered an ischemic cerebrovascular accident (stroke) with compromised blood flow (paragraph 121; discloses that "injury can be minimized and recovery hastened when hypothermia is instituted early following heart attacks and strokes, which is carried out by performing the same method as that of the instant application) and subsequent leakage of nitrogen into the intramitochondrial space of affected tissues causing an impairment in oxidative metabolism in said mitochondria, which comprises administering through a face mask (Paragraph 32) the inhalation of a nitrogen free gas mixture of oxygen and helium, each at 20-80% complimentary concentrations (paragraph 14; wherein it is stated that "the concentration of oxygen in the inspired gas mixture is preferably kept to at least 20%, with the remained of the gas mixture preferably being helium.") with exhalations being shunted through a one-way valve into the ambient atmosphere (Fig. 2; paragraph 114; disclosed that "the expired gas can be respired through an expiratory valve 148 and through expiratory limb 150) to effect a 50-90% or more washout of nitrogen from the body and body water until blood flow is restored to the compromised area and a subsequent washout of nitrogen from the affected tissues and mitochondria permits the return of said ischemic tissues to a state of oxidative metabolism (although not explicitly stated by Kumar et al, it is inherent that the method as disclosed by Kumar et al would in fact effect a 50-90% or more washout of nitrogen from the body and body water until blood flow is restored to the compromised area because the apparatus and method disclosed by Kumar et al anticipates every method step as claimed by the applicant and would therefore

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inherently effect the same outcome). It is not disclosed that the exhaled air is shunted through a one-way flutter valve." Bird et al discloses the use of a one-way flutter valve (10) in the exhalation flow path (abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the disclosed one-way valve of Kumar et al to a one-way flutter valve as disclosed by Bird et al because it well known in the art to be an effective type of one-way valve to regulate expired gas.

As to claim 4, Kumar et al disclose a process where the treatment is implemented as soon as possible following admission to the hospital and continued for 30 minutes up to 72 hours to assure optimum therapy and minimize cell death. (NEW)

As to claims 5 and 6, Kumar discloses a process wherein the gas mixture is 30% oxygen and 70% helium (In paragraph 14, Kumar discloses that the concentration of oxygen in the inspired gas mixture is preferably kept to at least 20%, with the remained of the gas mixture preferably being helium, which would include the 30% oxygen and 70% helium as claimed by the applicant.)

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure and cites references teaching the delivery of helium-oxygen gas mixtures to patients: US 6536429, US 2003/0106554, US 2004/0234610, and US 2006/0162725.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Amadeus S Lopez  
Examiner  
Art Unit 3771  
January 10, 2007

ASL

  
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1/15/07